

EXHIBIT B

Case 2:21-cv-10312-SJM-RSW ECF No. 1, PageID.1 Filed 02/10/21 Page 1 of

8

4 IN THE UNITED STATES DISTRICT COURT
2 EASTERN DISTRICT OF MICHIGAN

3

4 Stanley H. Kremen,
5 Attorney at Law
4 Lenape Lane
6 East Brunswick, New Jersey 08816
(732) 593-7294
7 Attorney for the Plaintiff

SOUTHERN DIVISION

TRUTEK CORP.,

Case No. 2:21-cv-10312

Plaintiff,

Hon. Stephen J. Murphy, III

v.

BlueWillow Biologies, Inc.
ROBIN ROE 1 through 10, gender neutral fictitious
names, and ABC CORPORATION 1 through 10
(fictitious names).

BLUEWILLOW BIOLOGICS, INC.,
et. al.

Defendants.

PLAINTIFF TRUTEK CORPORATION'S
AMENDED COMPLAINT

8

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CIVIL ACTION No. _____

COMPLAINT

DEMAND FOR JURY TRIAL

PARTIES

NOW COMES Plaintiff, TRUTEK CORP., by and through its attorneys, the Law Office of Stanley H. Kremen and The Law Office of Keith Altman, and for their Amended Complaint, hereby states the following:

PARTIES

Plaintiff, TRUTEK CORP., ("TRUTEK") is a corporation of the State of New Jersey, with principal offices at 281 East Main Street, Somerville, New Jersey, 08876.

2. Upon information and belief, Defendant, BlueWillow Biologics, Inc. ("BLUEWILLOW") is a corporation of the State of Delaware, with a place of business at 2311 Green Road, Suite A, Ann Arbor, Michigan 48105.

FEDERAL SUBJECT MATTER JURISDICTION

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²⁶ ³ The subject matter jurisdiction of this Court arises under 28 U.S.C. § 1331

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²⁷ concerning a federal question, the Patent Laws of the United States, 28 U.S.C. §§

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²⁸ 1338(a), (b), and 35 U.S.C. § 271.

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IN PERSONAM JURISDICTION

4. The *in personam* jurisdiction of this Court over Defendant BLUEWILLOW is proper under 28 U.S.C. § 1400(b) because the tort of patent infringement occurred in Michigan and BLUEWILLOW has an established place of business in Michigan.

#

VENUE

5. The venue of this Court is proper under the Patent Venue Statute, 28 U.S.C. § 1400(b) since the tort of patent infringement occurred within the State of Michigan, and Defendant BLUEWILLOW has an established place of business thereat, and which is furthermore located within the venue of the Eastern District of Michigan.

#

STATEMENT OF FACTS AND CAUSES OF ACTION

6. Ashok Wahi ("WAHI") is ~~President~~ Chief Science and IP Officer of Plaintiff TRUTEK.

7. On November 21, 1995, United States Patent No. 5,468,488 (hereinafter the '488

Patent) was issued to WAHI for his invention titled, "Electrostatically Charged

7. Nasal Application Product and Method." The '488 Patent was assigned to TRUTEK.

8. On October 7, 1997, United States Patent No. 5,674,481 (hereinafter the '481

8. Patent) was issued to WAHI for his invention titled, "Electrostatically Charged Nasal

Topical Application Product." The '481 Patent was assigned to TRUTEK.

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9. On January 18, 2005, United States Patent No. 6,844,005 (hereinafter the '005

Patent) was issued to WAHI for his invention titled, "Electrostatically Charged Nasal Application Product With Increased Strength." The '005 Patent was assigned to TRUTEK.

10. On April 24, 2012, United States Patent No. 8,163,802 (hereinafter the '802 Patent) was issued to WAHI for his invention titled, "Electrostatically Charged

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10. Multi-Acting Nasal Application Product, and Method," on a patent application that was filed at the United States Patent and Trademark Office (USPTO) on May 16, 2009. The '802 Patent was assigned to TRUTEK. The '802 Patent is attached hereto as Exhibit 6.

11. The patented technology made it possible for people to apply TRUTEK's manufactured products in and around their nasal passages to reduce reactions to airborne allergens and to reduce or eliminate reactions to viral infections from influenza and the common cold by restricting and inactivating virus sized particles. This is done by establishing an electrostatic charge in and around nasal passages.

12. As of the year 1992 going forward, TRUTEK utilized its patented and proprietary trade secret technology to establish proof of concept, develop, formulate, manufacture, sell, and/or license over-the-counter products under the brand name

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NasalGuard® AllergieBlock®, NasalGuard Cold&Flu Block®, NasalGuard® Multi Acting™, Anti-Stat Enhanced Mask™, NasalGuard Wipes™, NasalGuard Allergie

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Wipes™, NasalGuard Cold & Flu Wipes™, Skin and Hair super conditioners, Truteks® Skin and Truteks® skin care products, along with electrostatically charged nasal multipurpose products, nasal application (anti-stat) diagnostic products and, associated Technologies and Methodologies, Patents and Pending

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Patent Applications, also including products under the brand names Chloraseptic

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13. Allergen Block and Little Allergies Allergen Block, Eisai Crystal Veil, Eisai Crystal Veil Cool, Nitto Nuru Mask, Nitto NasalGuard, further including but not limited to nasal application product lines such as gels, pre-moistened products for *e.g.* applicators, swabs, wipes, etc., sticks, nasal sprays, nasal washes, surgical masks, and multi-acting/integrated products.

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13. Claim 1 of the '802 Patent claims a method of applying a formulation to the skin or tissue of a person's nasal passages in a thin film. The formulation attracts and holds particulate matter to the thin film, and binds it to the thin film. The bound

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68 13. particulate matter is then inactivated by at least one ingredient that renders it harmless.
 69 One such claimed inactivating ingredient is benzalkonium chloride (claim 7). This
 70 process is sometimes referred to as "catch, hold, and kill."

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71 14. Claim 2 of the '802 Patent claims a formulation that is applied to the skin or tissues
 72 of a person's nasal passages in a thin film. The formulation contains a cationic agent
 73 (an ingredient that produces a positive electrostatic charge) and a biocidal agent (a
 74 substance that destroys or inhibits the growth or activity of living organisms). The
 75 formulation electrostatically attracts and holds particulate matter to the thin film, and
 76 binds it to the thin film. The bound particulate matter is then inactivated by at least
 77 one ingredient that renders it harmless. One such claimed cationic agent is
 78 benzalkonium chloride (claim 6) and one such claimed biocidal agent is benzalkonium
 79 chloride (claim 7). This formulation functions using the process referred to as "catch,
 80 hold, and kill," *supra*.

BLUEWILLOW'S Nanobio® Protect Products

82 44-15. According to information and belief, sometime in 2020, Defendant
 83 BLUEWILLOW manufactured and marketed one or more over-the-counter
 84 pharmaceutical products named NanoBio® Protect ("NANO BIO"). According to
 85 information and belief, the NANO BIO products were sold over-the-counter at least at
 86 CVS pharmacies nationwide, and were sold online to customers by Amazon.com.

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87 48-16. BLUEWILLOW's website advertises the NANO BIO product being applied to a
 88 customer's nasal passages. Their product forms positively charged "NanoBio

Droplets" that are approximately 600 nanometers¹ in size, which adhere to nasal membranes. Most harmful particles, such as bacteria or viruses (referred to as "germs"), are negatively charged. The positively charged "NanoBio Droplets" attract and bind to these particles. The NANOBIO product formulation contains benzalkonium chloride (which the website calls BZK) that adheres to the surface of the "NanoBio droplets." According to the website, the "NanoBio droplets" surround the germs and "kill them via membrane disruption." (See Exhibit 1 attached hereto.) The NANOBIO product implements the methodology of "catch, hold, and kill." The NANOBIO website "Frequently Asked Questions" section (Exhibit 2) describing the product further enforces this mechanism of action.

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~~46-17.~~ Sometime in 2020, WAHI suspected that the NANOBIO product infringes one or more of TRUTEK's patents. To that end, on June 23, 2020, TRUTEK personnel purchased the NANOBIO product from Amazon.com. After extensive in-house experimentation, it was indicated that the NANOBIO product functions by producing an electrostatic charge in and around the user's nasal passages. It was indicated that NANOBIO product infringes claims of TRUTEK's '802 Patent. On January 14, 2021, TRUTEK personnel purchased a NANOBIO product from CVS, and obtained similar results through in-house experimentation.

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~~On January 14, 2021, TRUTEK personnel purchased a NANOBIO product from~~

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¹ A nanometer is a billionth of a meter.

~~CVS, and obtained similar results through in-house experimentation.~~

~~17.~~ To validate TRUTEK's in-house experimental results, TRUTEK contracted with

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~~Alexei~~ Alexei Ermakov, Ph.D. to compare the electrostatic charges between

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BLUEWILLOW's NANOBIO product and TRUTEK's NasalGuard®

products. His experiments showed not only that the NANOBIO product

exhibited a surface electrostatic charge, but also that the orders of magnitude

of the charges of the

BLUEWILLOW and TRUTEK products were of the same order of magnitude. Dr.

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Ermakov's Report is attached hereto as Exhibit 3. For further verification,

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~~18.~~ TRUTEK ~~contracted with Electro-Tech Systems ("ETS") in Perkasio,~~

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Pennsylvania, to run additional experiments. ETS personnel applied

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BLUEWILLOW's NANOBIO product and TRUTEK's NasalGuard® product to pig

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skin swatches. Pig skin is very similar to human skin tissue. The ETS and Ermakov

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experiments yielded similar results. The NANOBIO product exhibited a surface

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electrostatic charge of the same order of magnitude as the NasalGuard® product. The

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ETS report is attached hereto as Exhibit 4.

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~~18.~~ On January 31, 2021, Keith Altman, a resident of the State of Michigan,

ordered and paid for one unit of NanoBio Protect Nasal Antiseptic online

from

Amazon.com. The product was to be shipped by Amazon.com to his address

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in Michigan. Mr. Altman used his computer to place the order, and the

computer is located in Michigan, and it was located therein at the time that he placed his order. On February 1, 2021, Mr. Altman received the ordered one unit of NanoBio

19. Protect Nasal Antiseptic in Michigan at the designated Michigan shipping address. A declaration of Keith Altman attesting to these events is attached hereto as Exhibit 5.

~~19.~~ 20. The ability to lessen the reactions to airborne contaminants by creating an electrostatic charge around a person's nasal passages was disclosed in TRUTEK's '488, '481, '005, and '802 Patents. A copy of the '802 Patent is attached hereto as Exhibit 6.

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~~20.~~ 21. The ability to lessen the reactions to airborne contaminants by creating an electrostatic charge around a person's nasal passages is inherent in TRUTEK's formulations and manufacturing processes. Efficacy studies show that TRUTEK's methodology presented a viable solution to relief of allergy, cold, and flu symptoms.

~~21.~~ 22. Upon information and belief, just as TRUTEK's products work on allergens and viruses by creating an electrostatic charge around nasal passages and further inactivate said allergens and viruses, the NANOBIO products work the same way.

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23. At some point after this lawsuit was filed, BLUEWILLOW discontinued sales of the NANOBIO products, and the product descriptions were removed from BLUEWILLOW'S website.

~~22.~~24. The NANOBIO products ~~are~~were sold to customers by Amazon.com as are TRUTEK's competing products also sold thereby. The competitive sales of the competing NANOBIO products deprive TRUTEK of sales and profits from its own products.

~~23.~~— Upon information and belief, Defendants Robin Roe 1 through 10 and ABC ~~23.~~ Corporations 1 through 10 also infringe on the claims of TRUTEK's '802 Patent.

~~##~~

WILLFUL PATENT INFRINGEMENT

~~26.~~Plaintiff owns intellectual property relating to an electrostatically charged multi-acting nasal application product and method covered by the '802 patent.

~~27.~~Defendants distributed, made, used, offered to sell and/or sold infringing products, *i.e.*, the NANOBIO products.

~~28.~~Defendants distributed, made, used, offered to sell and/or sold infringing products, *i.e.*, the NANOBIO products, which infringe on the '802 patent, without authority or license from Plaintiff.

~~29.~~Defendants infringe at least claims 1, 2 and 7 of the '802 patent because the NANOBIO products possess an electrostatic charge when applied to a person's nasal passages, and they use benzalkonium chloride as a cationic agent and also as a biocidal agent.

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173 30. Defendants received notice that the NANOBIO products infringed on claims 1, 2, 6
174 and 7 of the '802 patent when Plaintiff filed the original complaint in this action on
175 February 10, 2021.

176 31. Defendants had knowledge of the '802 patent on the date of the original complaint in
177 the present action.

178 32. Defendants continued to market, distribute, and sell NANOBIO products for
179 approximately months after learning that the NANOBIO products infringed on claims
180 1, 2, 6 and 7 of the '802 patent. A copy of BlueWillow Biologics, Inc.'s, financial
181 records are attached hereto as Exhibit 7.

182 33. Defendants provided Plaintiff with copies of BlueWillow Biologics, Inc.'s, financial
183 records after the close of discovery.

184 34. Plaintiff has analyzed BlueWillow Biologics, Inc.'s financial records, and the records
185 establish by a preponderance of the evidence that enhanced damages are appropriate.

186 35. Defendants' actions constitute willful patent infringement under 35 U.S.C. § 284 and
187 35 U.S.C. § 285.

188 36. Under 35 U.S.C. § 284, when the damages are not found by a jury, the court shall
189 assess them; in either event the court may increase the damages up to three times the
190 amount found or assessed.

191
192 **GENERAL ALLEGATIONS**

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24-37. Plaintiff incorporates all of the above Paragraphs *supra* as though fully restated herein.

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28-38. Plaintiff owns intellectual property related to certain formulations based upon attracting and/or repelling electrostatically charged particles in and around a person's nasal passages by application of a product that maintains an electrostatic charge on the skin or mucous membranes. Plaintiff has expended considerable resources to inventing, formulating, and developing its inventions and products and to protecting its rights therein. Plaintiff holds all rights, title, and interest to its '488, '481, '005, and '802 Patents. The '802 Patent is in full force and effect. TRUTEK is the legal owner of the '802 Patent and possesses all rights of recovery under the patent.

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STATEMENT OF CLAIMS

COUNT 1

Infringement of the '802 Patent

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28-39. Plaintiff incorporates all of the above Paragraphs *supra* as though fully restated herein.

213 ~~27-40.~~ Plaintiff owns intellectual property relating to an electrostatically charged
 214 ~~multi-acting~~ multi-acting nasal application product and method covered by the '802
 215 patent. ▲

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216 ~~28-41.~~ Defendants ~~distribute, make, use, offer~~ distributed, made, used, offered to sell and/or
 217 ~~sell~~ sold infringing products, *i.e.*, the NANOBIO products. ▲

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218 ~~29-42.~~ Defendants ~~distribute, make, use, offer~~ distributed, made, used, offered to sell and/or
 219 ~~sell~~ sold infringing products, *i.e.*, the NANOBIO products, which ~~infringe~~ infringed on
 220 the '802 Patent, without authority or license from Plaintiff. ▲

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221 ~~30-43.~~ Defendants infringe at least claims 1, 2, and 7 of the '802 Patent because the
 222 NANOBIO products possess an electrostatic charge when applied to a person's nasal
 223 passages, and they use benzalkonium chloride as a ~~biocide~~ cationic agent and also as a
 224 biocidic agent. ▲

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225 ~~31-44.~~ Plaintiff has been damaged as a result of Defendants' infringement of the '802
 226 Patent, and will continue to be damaged unless such infringement is enjoined by this
 227 Court pursuant to 35 U.S.C. § 283. ▲

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228 ~~32-45.~~ Pursuant to 35 U.S.C. § 284, Plaintiff is entitled to damages adequate to
 229 compensate in an amount not less than a fair and reasonable royalty. ▲

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230 46. Alternatively, as the NANOBIO products are no longer being sold by Defendants,
 231 Plaintiff is entitled to damages adequate to compensate in an amount not less than the
 232 profits realized by Defendants for past sales of the NANOBIO products.

233 47. Pursuant to 35 U.S.C. § 284, Plaintiff is entitled to damages adequate to compensate
234 in an amount not less than a fair and reasonable royalty.

235 48. Plaintiff is entitled to a judgment from the Court, which enjoins sales or
236 commercialization by BLUEWILLOW of its NANOBIO products until after
237 expiration of the '802 Patent.

238 **COUNT 2**

239 **Willful Infringement of the '802 Patent**

240 49. Plaintiff incorporates all of the above paragraphs *supra* as though fully restated herein.

241 50. Plaintiff owns intellectual property relating to an electrostatically charged multi-
242 acting nasal application product and method covered by the '802 patent.

243 51. Defendants distributed, made, used, offered to sell and/or sold infringing products,
244 *i.e.*, the NANOBIO products.

245 52. Defendants distributed, made, used, offered to sell and/or sold infringing products,
246 *i.e.*, the NANOBIO products, which infringe on the '802 patent, without authority or
247 license from Plaintiff.

248 53. Defendants infringe at least claims 1, 2, 6, and 7 of the '802 patent because the
249 NANOBIO products possess an electrostatic charge when applied to a person's nasal
250 passages, and they use benzalkonium chloride as a cationic agent and also as a biocidic
251 agent.

54. Under 35 U.S.C. § 284, when the damages are not found by a jury, the court shall assess them; in either event the court may increase the damages up to three times the amount found or assessed.

55. Defendants had knowledge of the '802 patent on the date of the original complaint in the present action.

56. Defendants continued to market, distribute, and sell NANO BIO products for months after learning that the NANO BIO products infringed on claims 1, 2, 6, and 7 of the '802 patent.

57. Defendants' actions and financial records demonstrate that Defendants' conduct amounted to intentional or knowing infringement of the 802' patent.

58. Defendants' actions constitute willful patent infringement under 35 U.S.C. § 284 and 35 U.S.C. § 285.

59. Pursuant to 35 U.S.C. § 285, the court in exceptional circumstances may award reasonable attorneys' fees to the prevailing party.

PRAYER FOR RELIEF

Wherefore, Plaintiff prays that:

4-a) Defendants be required to pay over and account to Plaintiff for all gains, profits, and advantages derived from the infringement of its '802 Patent beginning April 24, 2012, based upon manufacture, sales, and/or use

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of the NANOBIO products in the United States and anywhere in the world,
or by way of international commerce with the United States.

2. Defendants be enjoined from manufacturing and/or selling the NANOBIO
b) products in the United States, either directly or indirectly.

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c) ~~1-3~~ Defendants be enjoined from actively inducing others to sell the
NANO BIO ~~2~~ products in the United States, either directly or indirectly.

~~3-4. Defendants be enjoined from exporting the NANO BIO products from the United 4 States, either
directly or indirectly.~~

5 5. Plaintiff prays for such other and further relief as the
Court may deem to be just

6d) and proper.

7 #

8 **DEMAND FOR DISCOVERY OF INSURANCE COVERAGE**

9 Pursuant to Defendants' discovery obligations, demand is made
that all

10 Defendants disclose to the Plaintiff whether or not there are any
insurance agreements

11 or policies under which any person or firm carrying on an
insurance business may be

12 liable to satisfy part or all of a judgment which may be entered in
this action or indemnify

13 or reimburse for payments made to satisfy the judgment and
provide Plaintiff with true

14 copies of those insurance agreements or policies, including, but
not limited to, any and

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all declarations sheets. This demand shall include and cover not only primary coverage, but also any and all excess, catastrophe and umbrella policies.

#

DEMAND FOR A JURY TRIAL

Plaintiff hereby demands a trial by jury of all issues triable of right by a jury.

Dated: ~~February 9, 2021~~ October 25, 2022 Respectfully submitted,

/s/ Stanley H. Kremen

Stanley H. Kremen, Esq.

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keithaltman@kaltmanlaw.com

Attorneys for Plaintiff, Trutek Corp.

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